IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT of WEST VIRGINIA
Beckley,

DONALD LEE TAYLOR, pro-se.
plaintiff
V.

CA NO. 5:03-2075
To Be Assigned

MARY YELINEK, Medical Administrator
CORRECTIONAL MEDICAL SERVICES,
JIM RUBENSTEIN, Commissioner,
THOMAS MCBRIDE, WARDEN,
MT. OLIVE CORRECTIONAL COMPLEX. AS,
WEST VIRGINIA DIVISION of CORRECTIONS
"ALL" Individual & Official Capacities
et.al. Defendent(s)

"Expedited Process Requested

★

42 U.S.C.A § COMPLAINT § 1983

★ ★

FOR HIS COMPLAINT AGAINST DEFENDENT(S), YOUR PLAINTIFF DONALD LEE TAYLOR, PRO-SE, ALLEGES AS FOLLOWS;

I. THE PARTIES;

1.) PLAINTIFF DONALD LEE TAYLOR; IS AT ALL TIMES RELEVANT HEREIN A Citizen of The STATE of WEST VIRGINIA and The UNITED STATES and at ALL TIMES RELEVANT to the ALLEGATIONS of his COMPLAINT WAS a Resident of Fayette County, WVA. Residing AT.; 1 MOUNTAINSIDE WAY, MT. OLIVE, WVA. 2518

2) Upon Information and Belief, Defendent Mary Yelinek, is a Person and a Resident of the STATE of WVa. and is/was at all Times Pertinent Hereto, Employed by Correctional Medical Services Corporation and the WVA. Division of Corrections at the MT. Olive Correctional Complex as the Medical Administrator; She is being Sued in her Individual Personal and Official Capacities; Her Business Address is 1 Mountain Side Way, MT. Olive WVA. 25185

3) Defendents' Correctional Medical Services is the Corporation who Employs Defendent Mary Yelinek as well as Thru Contractual Agreement with Defendent WVA. Division of Corrections to Provide Adequate Medical Care to Prisoners & Plaintiff at WVA. Prisons Including the MT. Olive Correctional Complex Facility; Defendent Correctional Medical Services is being Sued in its Individual, Personal & official Capacities and at All times Relevant to the Allegations In this Complaint has its Principle Place of Business at: 1 MT. Side Way, MT. Olive WVA. 25185

4) Defendent Jim Rubenstein A Person and A Resident of the STATE of WVA. is/was at all Times Pertinent Hereto; Employed by the WVA. Division of Corrections as the Commissioner of The WVA. Division of Corrections and Pursuant to the Laws of WVA. and the United STATES is Charged with the Oversight and Fair Treatment of All Individuals Including Plaintiff In All Prisons of WVA. Including the MT. Olive Correctional Complex Facility; He is being Sued in his Individual, Personal and Official Capacities; His Principle Place of Business is Situated at 112 California Ave, Bldg 4 Rm. 300, Chas WVA 25305-0700;

5.) Defendent Thomas McBride a Person and A Resident of the State of WVA. is/was at all Times Pertinent Hereto, Employed by the WVA. Division of Corrections AS The WARDEN of The MT. OLIVE Correctional Complex Facility and Pursuant to the Laws of WVA. and the United STATES' is Charged with the Oversight and Fair Treatment of All Individuals Including Plaintiff at the MT. OLIVE Correctional Complex facility, He is being Sued in His Individual, Personal & Official Capacities, His Principle Place of Business is Situated at; 1 Mountainside Way, MT. OLIVE WVA. 25185,

6.) Defendents WVA Division of Corrections / MT. OLIVE Correctional Complex is An Agency and or Political Sub-division of WVA. Department of Public Safety That Employed or Employs The Defendents Mary Yelinek, Correctional Medical Services, Jim Rubenstein & Thomas McBride, And has its Principle Place of Business Situated at; 112 California Ave, Bldg. 4, Rm. 300, Chas. WVA 25305-0700;

7.) Defendents and Each of Them Seperately and In Concert are all being Sued under and up unto the Limits of their Insurance Coverage Policies - Furthermore At All Times Relevant Hereto and in All Their Actions described Herein, These Defendents and Each of Them Seperately and In Concert acted Personally [Under Color of STATE LAW], or Executive officers Personnel, "All" Allegations In This "Complaint" ARE made Against All the Defendents Except where otherwise noted.

II. JURISDICTIONS 42 USC § 1983

8.) JURISDICTION of THIS ACTION is founded in 28 USC § 1331, 1343 1334(4), and 1361 for a Title 42 USCA § 1983, [42 USC § 1983]; for damages Sustained by A Citizen / Citizens of The UNITED STATES against EMPLOYEE'S of, Defendents CORRECTIONAL MEDICAL SERVICES and THE WVA. DIVISION of CORRECTIONS AS PERSONNEL and Their EMPLOYERS, Each is Sued AS A PERSON FOR Compensatory and Punitive damages DECLARATORY Judgement and INJUNCTIVE RELIEFS for Subjecting Plaintiff to SERIOUS RISKS of HARM to His Health and SAFETY, Physical damages and DETRIMENT to his OVERALL Health by MAINTAINING UNCONSTITUTIONAL PRACTICES and CUSTOMS Regarding Medical CARE / TREATMENT, by failing and Refusing to Provide Plaintiff with "Adequate" Medical CARE, follow up CARE or otherwise by "Qualified" and TRAINED PERSONNEL to MAKE PROFESSIONAL determinations Regarding Plaintiffs SERIOUS Medical ILLNESS of Hepatitus (C) LIVER DISEASE ~ Defendents are RESPONSIBLE because of Their Conduct, Authorization, Condonation, and or Ratification AS Applicable, of the ACTS and OMISSIONS of The Individual Defendents ACTING [UNDER Color of STATE LAW] and PERSONALLY IN depriving MR. Taylor Rights Secured to Him by The CONSTITUTIONS of WEST VIRGINIA and The UNITED STATES and the Laws of WEST VIRGINIA by INTER al

9.) Subjecting MR. Taylor to CRUEL and UNUSUAL PUNISHMENTS and SERIOUS RISKS to His OVERALL HEALTH and SAFETY by the MAINTAINING of UNCONSTITUTIONAL PRACTICES and Customs Regarding Medical CARE, TREATMENT, denying, failing and Refusing to ENSURE Plaintiff RECEIVE Adequate Medical CARE * TREATMENT, follow up CARE or otherwise by

... "Qualified" and Trained Personnel Qualified to make Professional determinations Regarding Plaintiffs Serious Medical Illness of Hepatitus (C) Liver disease; The Rights having been Violated and Sought to be Enforced Herein Include A deprivation of Plaintiffs Rights Protected Under (Article III Sections 5 & 10) of The West Virginia Constitution and The Fifth, Eighth and Fourteenth Amendmen to the United States Constitution.

III. Brief Summary of Case facts;

10.) In November 1999 Plaintiff Tested Positive for Hepatitus (C) Liver disease with Elevated (ALT.) Liver Enzymes, (Elevated (ALT) Enzymes are damaged Liver cells been Released into Plaintiff Bloodstream);

11.) The Court Should note That Initially it took Plaintiff Several Months to Obtain - Blood Test Results Medical Records Because Defendent maintain a Practice of Refusing to disclose such when Treatment care determinations are Indicated Because Defendents Routinely maintain the Practice of denying needed Medical Care based upon "Cost Reasons",

12.) After Repeated delays and denial of Treatment determinations Plaintiff finally Under went a Liver Biopsy Test In April 2001 which Indicated Plaintiff Suffered from Increased Portal Inflammatio with Feathery Changes Beginning to Manifest In Plaintiffs Liver.

13.) ON (May 9, 2001) It was determined Plaintiff was a Candidate for Hepatitus (C) Treatment Therapy which Initially began with (Peg-Intron Treatment) IN (June 2001,) (See Plaintiffs Ex. # 1);

14.) After Approx. Eight (8) months of Treatment Therapy with (Peg-Intro Plaintiff failed to Respond to Therapy.

15.) IN Approx. (February 2002): Plaintiff began "Combination Therapy" with (Peg-Intron & Ribavarine) or (Rebetol); & within Three (3) month Plaintiff Responded to Therapy; (Treatment Shots of "Peg-Intron" are to be given once weekly), (Ribavarin/Rebetol) comes in Capsul and are administered (twice daily); Treatment Continues for those who Respond for up to Twelve (12) months for Patients like Plaintiff who are Genotype (1) Hep. (C) Virus

16.) Plaintiffs Combination Treatment Therapy Continued up until (February 2003), Yet during Plaintiffs Course of Treatment Defendents Routinely "Skipped" Plaintiffs weekly Treatment Shots (for weeks at a time) giving the virus time to "Replicate" or ("Bounce Back Each Time Treatment Shots were Skipped and untimely delayed"); within A month after Treatments End or Approx. March 2003; Plaintiff "Relapsed" from Treatment. (See Plaintiffs Ex. "2");

17). Based upon Information and Belief, Patients Like Plaintiff wh Respond To Therapy, Then Relapse generally Respond Again with Continued Therapy (See Plaintiffs Ex. "3");

18.) The Court Should NOTE There are Currently only Two (2) Basic STANDARDS of Interferon Medical Care Treatment Available for Plaintiffs Current Medical Condition which ARE, (① Peg-Intron & Ribavirin Combination Therapy) & (② Pegasys plus Copegus); both TREATMENTS Administer WEEKLY Treatment Shots ~ However Peg-Intron Comes In Powder form that Requires RECONSTITUTION to become Liquid for Injection, AS A Result This form of Interferon is "UNSTABLE" and "WEAKLY Attaches to the Interferon Molecule".

19.) "Pegasys' Interferon on the otherhand is A Result of A Later Pegylation Technology which Comes In an ALREady Soluable form which USES a Larger BRANCHed Peg That "Very Tightly" Attaches to the Interferon AND it is "Very Stable" which Provides Constant SUPPRESSION of The Hep(C) VIRUS from the first dose Injected to when Therapy is Completed;" In Support of These Medical facts (See Plaintiffs Ex "4"); overall "Pegasy's" is Primarily Twice as Efficient Providing for Chances of A Better and overall Sustained Response (See Plaintiffs Ex "4") Id (at p 4 in Chart).

20.) AS NOTED Plaintiff has ALREady been Treated with Peg-Intron & Responded, Yet due to this Type of Interferons Ineffectiveness Combined with Defendents (CMS) (Repeated "Skipping" Plaintiffs WEEKLY Treatment Shots during Course of Treatment) Plaintiff ReLapsed (Plaintiffs Ex "2").

21.) Plaintiffs STANDARD of Treatment now becomes (Pegasys plus Copegus

22.) From (April 2003 to June 2003), Plaintiff Exhausted All Grievance Process & Administrative Remedies Pertaining to the Claims In This Complaint; Yet Defendents have made it Clear They have no Intention of Treating Plaintiffs Serious Medical Needs with Knowing, Intentional and deliberate Intent to Cause Plaintiff Harms (See Plaintiffs Ex. #5);

23.) Plaintiff is Enduring Needless "Pain and Suffering" and Extrem Substantial "Physical damages to his Liver and overall Health" by Defendents Blatant Refusals to Provide Plaintiff with Adequate Medical Care, follow-up Care, Retreatment or otherwise which Requires Redress from this Honorable Court.

★ — "COUNTS ONE" — ★

— Defendents Mary Yelinek and Correctional Medical Services Deprivations of Plaintiff Donald Lee Taylors Civil Rights Under 42 USC §1

24.) MR. Taylor ReAlleges All Proceeding Paragraphs of This Complaint And Further Alleges that at All Times Relevent Hereto; And In All their Actions described Herein That Defendents Mary Yelinek and Correctional Medical Services were on duty and Acting Under Color of State Law.

25.) These Defendents and Each of Them were and are Obligated under the Laws of West Virginia and within the Framework of the U.S. and

.. United States Constitutions to Provide Adequate medical care Treatment and Adequate follow up Care to Prisoners Including Plaintiff At the Mt. Olive Correctional Complex facility but have refused to do So

26.) These Defendents and Each of Them Knew or Should of Known that Refusing and failing to Provide Plaintiff with the Basic Standards of medical Care Treatment, "Skipping" Plaintiffs weekly Treatment Shots of Peg-Intron, Failing and Refusing to Provide Plaintiff with Continued Treatment, Reevaluation of Treatment, Re-Treatment, follow-up care or otherwise would be very detrimental to Plaintiffs Liver and overall Health would Place Plaintiff Twice In Jeopardy of Life and Limb, Put Plaintiffs Health and Safety At Serials Risk and Threat of Continu Harm and Imminent danger by Permitting Plaintiffs Hepatitus (C) Liver Disease virus to Replicate Bounce Back and become Harder to Treat and would be A Clear Violation of Plaintiffs Constitutional Rights that have been Clearly Established within the framework of the USA and United States Constitutions.

27.) The Personal Conducts of These Defendents Refusals and Failures to Perform their Obligations Placed upon Them by the Laws of USA, within the framework of the USA and United States Constitutio Amounts to Gross Negligence, Callous Inattention, and Deliberate Indifference to Plaintiff and his Serious Medical Needs for his Hepatitus Liver Disease In that the Conducts of these Defendents Impinges on the Rights of Plaintiff which is a direct and Proximate Cause In the deprivation of Plaintiffs Constitutional Rights

28.) As A direct and Proximate Result of These defendents Conducts MR. Taylor has and Continues to Suffer Injuries Including the followin deprivations and Serious Harms; (a). Extensive Liver cell damage, (b) Increased Infection, (c) Permanent Physical damages to Plaintiffs overall Health in that the Vitality of Plaint Health is now Permanently Ruined, (d) Loss of Ability to Enjoy Life, (e) Extreme physical mental/Emotional Pain and Suffering (Past and future) (F). Humiliation, Stigmatization, dehumanization and (g) Substantial other Injuri for which Plaintiff Donald Lee Taylor is Entitled to Recover "Civil Righ violations"!

★ — "Counts Two" —

— Defendents Jim Rubenstein, Thomas McBride and West Virgini Division of Corrections Deprivations of Plaintiff Donald Lee Taylors Civil Rights Under 42 USC 1983. —

29.) MR. Taylor ReAlleges All Proceeding Paragraphs of This Complaint And Further Alleges that at All Times Relevant Hereto And In All Their Actions described Herein That Defendents Jim Rubenstein, Thomas McBrid and WVa. Division of Corrections Were on Duty and acting Under Color of State Law.

30.) These Defendents and Each of Them were and are Obligated Under The Laws of West Virginia and within the Framework of The WVA. and United States Constitutions To Ensure Plaintiff Receives Adequa Medical Care/Treatment, follow-up Care, or otherwise by Qualified medic

... Personnel but have Refused to do So;

31.) These Defendents and Each of Them Knew or Should have Known that denying and Refusing to Ensure That Plaintiff Received Adequate Medical Care/Treatment follow up Care or otherwise would be very detrimental to Plaintiffs Liver and overall Health, would Place Plaintiff Twice In Jeopardy of Life and Limb, Put Plaintiff at Serious Risks and Threat of Continued Harm and Imminent danger to his Health and Safety by denying and Refusing to Ensure Plaintiff Received Adequate Medical Care/Treatment for his Serious Medical Illness of Hepatitus(C) Liver disease and That In Refusing their Obligations to Plaintiff would be A Clear Violation of Plaintiffs Constitutional Rights That have been Clearly Established within the framework of The W.V.A. and United States Constitutions.

32.) The Personal Conducts of These defendents Refusals and failures to Perform their Obligations Placed upon Them by the Laws of W.V.A. and within the framework of The W.V.A. and United States Constitutions Amounts to Gross Negligence, Callous Inattention and Deliberate Indifference to Plaintiff and his Serious Medical needs for his Hepatitus(C) Liver Disease In that the Conducts of These defendents Impinges on the Rights of Plaintiff Which is A direct and Proximate Cause In The deprivation of Plaintiffs Constitutional Rights.

33.) As A direct and Proximate Result of These Defendents Conducts Mr. Taylor has and Continues to Suffer Injuries Including the following deprivations and Serious Harms; (2) Extensive Liver Cell damage,

... (b.) Increased Infection, (c) Permanent Physical damages to Plaintiffs overall Health in that the Vitality of Plaintiffs Health is now permanently Ruined, (d.) Loss of Ability to enjoy life, (e) Extreme Physical mental and Emotional Pain and Suffering (Past and future), (f.) Humiliation, Stigmatization, dehumanization, and (g). Substantial other Injuries for which Plaintiff Donald Lee Taylor is Entitled to Recover "Civil Right Violations"!

★ — "Counts Three and Four" — ★

Compensatory and Punitive Damages

34.) The Actions of Correctional Medical Services, Mary Yelinek, WVA. Division of Corrections, Jim Rubenstein, and Thomas McBride In Their Official and Individual Capacities have Violated Plaintiffs Constitutional Rights Guaranteed Under Art. III § 10 of the WVA Constitution and the Fifth, Eighth and Fourteenth Amendments to the United States Constitution.

35.) The Conducts of Defendents and Each of Them is Reprehensible, Wilfull and Wanton, Maliciously Oppressive and In Blatant Intentional disregards to Mr. Taylors Constitutional Rights Thereby Justifying An Award of Compensatory and Punitive Damages.

★ — "Counts Five" — ★

Declaratory Judgements

36.) Mr. Taylor seeks a declaration from the Court as to the Amount of Coverage Available to Plaintiff based upon the facts Perpetrated

... by the Individually NAMED DEFENDENTS WERE WITHIN THE SCOPE of EMPLOYMENT, AS WELL AS ANY other declaratory RELIEF RELATED to the COVERAGE QUESTIONS THAT might be developed IN THIS CASE.

WHEREFORE PLAINTIFF DONALD LEE TAYLOR demands JUDGEMENT AGAINST EACH of THE ABOVE NAMED DEFENDENTS JOINTLY and SEVERALLY AS follows:

1.) AN AWARD of COMPENSATORY and PUNITIVE DAMAGES to PLAINTIFF IN AN AMOUNT determined by A JURY.

2.) AN AWARD of REASONABLE COST and EXSPENSES to PLAINTIFF HEREIN; INCLUDING ATTORNEY FEES PURSUANT to [42 USC § 1988]

3.) AN AWARD of PRE-JUDGEMENT INTERESTS ON ALL SPECIAL DAMAGES AWARDED by A JURY. AND;

4.) ANY AND ALL declaratory OR other EQUITABLE RELIEFS this COURT DEEMS APPROPRIATE;

PLAINTIFF DONALD LEE TAYLOR DEMANDS A TRIAL by JURY ON ALL ISSUES SO TRIABLE.

Respectfully Submitted.

By Donald Lee Taylor

August 12, 2003

DONALD LEE TAYLOR #15593
MT. OLIVE CORRECTIONAL COMPLEX
1 MT. SIDE WAY (Q-4-713)
MT. OLIVE, WVA. 25185

Taylor v. Yelinek, et al.

CA. NO.

To be Assigned.

Exhibits

1 - Thru - 5

August 12, 2003

CMS
Mount Olive
Correctional Center

Memo

Ex. #1

To: Donald Taylor, DOC 15593

From: Medical – Dr. R. Slade

CC: file

Date: 05/09/01

Re: Hepatitis C Therapy

Mr. Taylor:

1. You are a candidate for treatment for your Hepatitis C. Your initial treatment will be with Peg-Interferon as a single drug therapy.

2. You have been informed that the drug can have side effects, some being very serious, and even may cause death. Some common side effects are: feeling of excessive tiredness, difficulty sleeping, joint pains, headache, a loss of appetite, depression, feeling anxious and irritable. More serious side effects are: loss of memory, loss of hearing, and infections. Life threatening side effects: such as suicidal impulses, convulsions, heart attack, kidney failure, it can also cause a decrease in red blood cells and white blood cells, leading to a decrease in immunity and blood clotting.

3. You will be having blood tests regularly, more often at first. You will be followed closely be medical personnel during treatment.

4. If you develop any serious side effects, your treatment may stop. If you have NO response to treatment in a period of time (usually 3 to 6 months) your treatment will be stopped.

5. You may stop treatment by your own choice. You may not be able to start treatment again.

6. Urine tests for a urine drug screen may be done at times during your treatment. These tests are not for the DOC, but for treatment purposes.

7. You must have a minimum of 12 months remaining, pre-parole/release, to begin treatment. Your first treatment may last up to a year.

8. Your TREATMENT for Hepatitis C MAY CAUSE YOUR DEATH.

NOTE: I
Stay b
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to meet

9. You Donald Taylor, DOC 15593 verbalize understanding of the side effects and instructions listed above and knowingly consent to treatment of Hepatitis C.

10. This agreement will remain a part of your medical record.

SIGNED: Donald B Taylor DOC#: 15593

Witness: [signature] Date 5/7/07

LabCorp
Laboratory Corporation of America

Laboratory Corporation of America

SPECIMEN	TYPE	PRIMARY LAB	REPORT STATUS	
076-231-8374-0	S	CB	COMPLETE	Page #: 1

ADDITIONAL INFORMATION

FASTING: N
DOB: 7/24/1962

PATIENT NAME	SEX	AGE(YR./MOS.)
TAYLOR,DONALD	M	40 / 7

PT. ADD.:

DATE OF SPECIMEN	TIME	DATE RECEIVED	DATE REPORTED	TIME	
3/17/2003	13:55	3/17/2003	3/26/2003	15:37	3018

CLINICAL INFORMATION
CD- 94105646356

PHYSICIAN ID.	PATIENT ID.
SLADE R	15593

ACCOUNT: MT OLIVE CORRECTIONAL CENTER
ATTN: APRIL MOORE
1 MOUNTAIN SIDEWAY / PO BOX 39
MT OLIVE WV 25185-0000
ACCOUNT NUMBER: 47101445

TEST	RESULT	LIMITS	LAB
NGI HCV QUANTASURE			
Copies/mL	Copies/mL		DE
Greater than 5,000,000 Copies/mL.			
International Units	IU/mL		
Greater than 2,000,000 IU/mL.			
Test Information			DE
PCR assay performed using National Genetic Institute's validated, proprietary methodology. Results greater than or equal to 5 Copies/mL of HCV RNA indicate the presence of virus-specific nucleic acid sequence.			

4/3/03

LAB: DE NATIONAL GENETICS INST LABCORP DIRECTOR: DONALD SIMPSON R
2440 S SEPULVEDA SUITE 130, LOS ANGELES, CA 90064-0000

Copy for Mr. D. Taylor when results reviewed w/ him.

NOTE: "Plaintiff swears under "Penalty of Perjury" that he has Lost Nearly (25 lbs) and Suffers Extremely From Body Aches and Pains Both Physical & Mental

Ex # 2

By Plaintiff

Results are Flagged in Accordance with Age Dependent Reference Ranges
Last Page of Report

I have placed you on our newsletter mail list

Yes!

HEP (C) AWARENESS NEWS
P.O. BOX - 41803
EUGENE, OR. 79404

APRIL 25, 2003

Ex. #3

RE: "Latest NEWS"

DEAR AWARENESS

Could you Please Provide me with Any Information Requested. The Latest NEWS In Hep (C) Treatments, - And Could you Also Answ A Question I have Regarding "Relapse" To Treatment Therapy;

" Say A Patient Responds To Treatment "Combination" (Peg - Intr Ribavirin or Rebetol,) Is Treated for (12) Months and Then (Relapses) (within (2) months After Treatment Has Stopped) Ar A Patient Responed Again with further Therapy? and if So, How L Should it be before Treatment begins Again? Any Information you Could Provide me In This Required would be Very much APPREC

Thank you for your Time

SINCERELY.

By Donald Lee Taylor

Donald Lee Taylor #15583
MT. OLIVE C.C.
1 MT. SIDE WAY. - Q-II-71
MT. OLIVE, WVA. 25185

All your start Treatment with the Regulated Interferons Plus Ribavirin will have a better chance at receiving a sustained response

June 2003
vol. 6, issue 6

HCV ADVOCATE

A MONTHLY NEWSLETTER OF THE HEPATITIS C SUPPORT PROJECT

www.hcvadvocate.org

Ex. #

Considering HCV Treatment?

Know Your Genotype and Viral Load

Alan Franciscus, Editor in Chief

In the past, many reports listed the overall sustained virological response (SVR) rates of HCV medications regardless of genotype—this was misleading because SVR rates are dramatically affected by genotype. Now, many physicians quote the pivotal trial results of currently available HCV therapies by genotype. However, a physician recently pointed out that the data now demonstrates that the amount of HCV RNA in the blood (viral load) also affects treatment response rates and commented that this is an important consideration to include along with genotype when interpreting HCV treatment response rates. In this article, I will review the current data available on sustained virological response rates broken down by genotype and viral load.

HCV RNA – Viral Load

HCV Viral load tests measure the amount of HCV circulating in the blood. HCV viral load is expressed as either copies per milliliter of blood or as a standard unit of measurement called International Units (IU). HCV viral load tests are used to confirm active HCV infection, to predict medical treatment response, and to measure how well HCV medications are working.

A low viral load (LVL) is defined as <2 million copies/ml or 800,000 IU/ml and a high viral load (HVL) is defined as >2 million copies/ml or 800,000 IU/ml. Even though the pivotal pegylated interferon combination trials used different assays, in general a low viral load (LVL) is defined as < 2,000,000 copies/ml. or 800,000 IU/ml. For exact conversions by assay please refer back to the May *Advocate Newsletter.*

Genotype

HCV has many different strains called genotypes. There are enough genetic differences to classify them into six major genotypes: 1, 2, 3, 4, 5, and 6. Genotype information is important when considering HCV treatment since some genotypes respond more favorably to medications than others with, non-1 genotype responding more favorably. Genotype also determines the length of therapy needed with genotype 2 and 3 requiring only 24 weeks in comparison to genotype 1 and 4 require 48 weeks. At this time there is not enough data to make definitive recommendations on other genotypes.

Genotype and Viral Load

Breaking HCV down by genotype and viral load in the United States further clarifies the issues of treatment response rates: genotype 1 comprises 74% of the overall population—49.5% with a high and 24.5% with a low viral load. That means that two-thirds of patients with genotype 1 have genotype 1 high viral load or to look at it another way—one-half of the U.S population with hepatitis C have genotype 1 high viral load. This contrasts with 26% of the population with genotype non-1—of which 17.4% have a high and 8.6% have a low viral load.

Therefore in the United States, regardless of genotype, two thirds of the hepatitis C population has a high viral load.

Standard of Care – PEG Plus Ribavirin

Pegylated interferon and ribavirin is now the standard of care for the treatment of hepatitis C. There are two available pegylated interferon combinations, Peg Intron (pegylated interferon alpha 2b – Schering Plough) plus Rebetol (Schering's branded ribavirin) and Pegasys (pegylated interferon alpha 2a – Roche) plus Copegus (Roche's

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IN THIS ISSUE

Ex. # 4

Websites

Lucinda K. Porter, RN, CCRC

It is common for patients to use the Internet. The "Web" can be a source of useful as well as misleading information. The Internet should never replace medical advice, but it can sometimes enhance medical knowledge. This month's article contains a compilation of some web sites that have made it to my "favorite" list. For those without Web access, many public libraries offer Internet service. Also, neither the HCV Advocate nor I endorse particular products or advertising connected with these web sites. If privacy is a concern for you, some of these sites require registration. Revealing your email address can put you at risk for unsolicited email (called "spam"). Finally, a word of caution - excessive computer use can have a negative impact on one's health. Remember to take breaks. Walk, stretch, rest your eyes, and engage in other activities.

My favorite hepatitis web site is unlikely to surprise any regular HCV Advocate readers. A colleague recently described the HCV Advocate web site as "one stop shopping for information about hepatitis C." This site is constantly updated. There are articles written by experts from a variety of fields, including information about support groups, disability, hepatitis B, and HIV/ HCV coinfection. There are many other fine hepatitis C-related web sites, too many to list in this article. I recommend starting with the HCV Advocate home page and linking to other sites from there: **www.hcvadvocate.org.**

A colleague recently described the HCV Advocate web site as "one stop shopping for information about hepatitis C." This site is constantly updated. There are articles written by experts from a variety of fields, including information about support groups, disability, hepatitis B, and HIV/ HCV coinfection.

For general medical information, I recommend Healthfinder. This site is provided by the United State's Office of Disease and Health Promotion: **www.healthfinder.gov.** The Medical Library Association has listed Healthfinder as one of the "top ten" most useful web sites. The list includes other web sites that I would include on my list, such as the Mayo Clinic **www.mayo.edu,** and Medline **www.medlineplus.gov.** This list can be accessed from Healthfinder's home page.

Another informative web site is Web MD: **www.webmd.com.** This web site is easy to use and usually provides good basic information. There is a link to Medscape, another web site worth exploring. For more in-depth research, the National Library of Medicine has a web site known as PubMed: **www.ncbi.nlm.nih.gov/PubMed.**

The Internet can provide useful tools for health promotion. Prevention magazine's web site offers a variety of articles ranging from recipes to tools for calculating calories and body mass index: **www.prevention.com.** The United States Department of Agriculture (USDA) has a food database on its web site. The database can be downloaded to personal computers or personal digital assistants (PDA):**www.nal.usda.gov/fnic/foodcomp.**

RealAge.com provides interesting health assessment tools. These tools can motivate making health changes: **www.realage.com.** Another creative Internet source encompassing the concept of change is "my goals.com." For those wanting a boost with achieving their goals, check out **www.mygoals.com.**

For those interested in herbs, HerbMed is packed with information: **www.herbmed.org.** Consumer Lab offers an excellent service for those interested in the quality of supplements. This subscription-based web site is growing. Some general information can be accessed without a subscription: **www.consumerlab.com.**

Finally, life is not complete without some humor. There are many web sites devoted to this topic. Laugh Lab struck me as amusing: **www.laughlab.co.uk.** Another diversion is **www.laughter.com.** Enjoy!

continued from page 4

with Peg Intron plus Rebetol combination therapy in the doses studied. It is also interesting to note that the genotype non-1 efficacy in high viral load patients is also no better than Rebetron. In summary two thirds of the patients in the United States with hepatitis C have no increased efficacy with Peg Intron plus Rebetol in the doses studied in Schering's development program.

One could argue that if higher doses of Rebetol were used in the original trial then the results would be better across all patients but is that really true? A retrospective analysis of the pivotal trial which is included in the *Lancet* publication looked at a subset of patients that received >10.6mg/kg of Rebetol. Because everyone in the prospective trial recieved only 800mg of Rebetol, the retrospective analysis was only looking at a subset of patients that were lighter, probably female who have prognostic factors in their favor for an SVR. To extrapolate the results from that subset across all patients is not a medically sound approach to a retrospective analysis and so Schering is now trying to prospectively look at this and a very large trial known as the WIN-R trial is underway. According to FDA documents the reason that Schering did not originally study higher doses of Rebetol in the Peg Intron 1.5µg/kg arm is that they were concerned about potential additive drug toxicities. The original pivotal trial had a dose modification rate of 42% with only 800mg Rebetol, which is sure to increase with higher doses of Rebetol. This issue however may be overcome in the WIN-R trial as it does allow for the use of growth factors such as erythropoietin (EPO) and granulocyte macrophage colony-stimulating factor (GM-CSF). But how available are they to the general population with hepatitis C?

Pegasys plus Copegus

Now let's review the data on Pegasys 180µg plus 1000-1200mg Copegus. Roche conducted two trials, the first is published in the *New England Journal of Medicine* 2002; 347(13):975-82 and the second was presented at EASL 2002 by Hadziyannis and is awaiting publication. Both studies are included in the FDA approved USPI. **See Table 2 for results.**

The data for Pegasys plus Copegus shows a marked improvement over standard interferon plus ribavirin combination in all patient types regardless of genotype or viral load. So why the difference in the results between the PEGs?

A Peg Is Not a Peg

Many people refer to the two pegylated interferons as though they are the same products but manufactured by different companies—based upon the prospective data that is available to date this doesn't seem to be the case. Interestingly, the information that was brought to my attention as it relates to the differences in the PEG's efficacy in high viral load patients may explain the differences in the PEG's. It is believed that this difference is a result of the different types of pegylation processes used by each company. Peg Intron is the result of earlier pegylation technology using a smaller linear peg that weakly attaches to the interferon molecule, which is the reason that Peg Intron comes in a powered form that requires reconstitution—it is unstable. This type of pegylation helped in the fact that Peg Intron doesn't need to be dosed three times a week, but it still acts similarly to standard interferon with periods at the end of each week when there is no detectable Peg Intron. It has not been determined how much interferon is needed to suppress the hepatitis C virus but one could theorize that if there is no drug in the body of someone with a high viral load—there is an opportunity for the virus to replicate, mutate and bounce back. This may explain the lack of improvement in response rates of Peg Intron over standard interferon in patients with a high viral load regardless of genotype.

Pegasys on the other hand is the result of later pegylation technology which uses a larger branched peg that very tightly attaches to the interferon, which explains why it is stable enough to be made in a ready made liquid formulation—it is very stable. This type of pegylation provides Pegasys with constant suppression of the hepatitis C virus from the first dose injected to when therapy is completed. Levels of Pegasys gradually increase until around week 5-8 when steady state is established

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Clinical Trials – Prospective vs. Retrospective

The most reliable research results come from a prospective study, which is carefully planned and conducted in a standard manner with well-defined patient populations as well as a protocol that includes predetermined primary and secondary endpoints. This is considered the gold standard of clinical research. On the other hand, a retrospective study looks back in time, which is subject to bias because certain assumptions are made that may not be valid. For instance, a retrospective study may look at previous study results and try to ascertain if treatment response rates would be improved using a higher dose of the study drug. However, you can not draw any concrete conclusions since you did not actually study the tolerability at a higher dose in all participants. Retrospective studies are, however, useful in determining what should be studied prospectively and therefore do have a role in medical science.

Noninvasive Markers for Liver Fibrosis

Liz Highleyman

A liver biopsy, in which a small sample of tissue is extracted with a needle and examined under a microscope, is considered the "gold standard" for gauging the extent of liver damage in people with chronic hepatitis. Biopsies can detect tissue changes that indicate fibrosis and cirrhosis. Traditionally, because interferon-based treatment for hepatitis C has been only moderately effective and comes with considerable side effects, most experts have recommended that people with minimal fibrosis should not be treated, and liver biopsy has been considered the best method for making such a determination. Repeated biopsies (every 3-5 years) are used to determine how fast fibrosis is progressing and whether treatment is working.

But liver biopsy is an invasive and expensive procedure that causes pain for about one-third of patients, and anxiety for many more. In addition, though rare (less than 1%), biopsy complications can occur, including excessive bleeding and infection. And, even under the best of circumstances, biopsies fail to accurately diagnose the stage of liver fibrosis about 20% of the time. Thus, researchers have sought other markers that could signal liver damage without the need for biopsy.

A number of factors have been associated with a greater risk of liver fibrosis, including older age, male sex, and alcohol consumption. Elevated levels of alanine transaminase (ALT), a liver enzyme, are associated with liver inflammation, but are not a good indicator of fibrosis. Some of the biochemical markers that have been proposed as indicators of liver disease progression include alpha2-macroglobulin, apolipoprotein A1, haptoglobin, bilirubin, gamma-glutamyl-transpeptidase (GGT), cholesterol, platelet count, and prothrombin time. Is it possible to develop an algorithm to estimate the extent of liver damage using easy, widely available, and inexpensive noninvasive measurements?

Different research teams have studied various indices, or combinations of biochemical markers, comparing index readings with biopsy results to see how well they agree about the extent of fibrosis. Dr. Thierry Poynard and colleagues from Paris have derived an index called FibroTest, which includes alpha2-macroglobulin, apolipoprotein A1, haptoglobin, total bilirubin, and GGT, as well as age and sex. They reported in the April 7, 2001 issue of *The Lancet* that for people with very low scores (below 0.10 on a scale of zero to 1.00), the index has a negative predictive value as high as 100% (that is, it says fibrosis is not present when in fact it is not). The positive predictive value for scores above 0.60 is over 90% (that is, it correctly says fibrosis is present when in fact it is). In the March 28, 2003 issue of *AIDS*, Poynard's team reported that FibroTest also accurately predicts liver fibrosis in people with HCV/HIV coinfection, and they reported in the March 2002 *Journal of Viral Hepatitis* that index scores decreased in patients who achieved a sustained virological response to interferon treatment. Use of the five FibroTest variables plus ALT—a combined index called ActiTest —allows for the prediction of inflammatory activity along with fibrosis. (For more on FibroTest and ActiTest, see **www.biopredictive.com.**)

> ***Both Fibrotest and Forns' index are very good at predicting the absence of fibrosis in people with low scores, but somewhat less so at accurately diagnosing the presence of liver damage in people with high scores.***

Dr. Xavier Forns and colleagues from Barcelona have developed a fibrosis index that includes age, GGT, platelet count, and cholesterol levels. They reported in the October 2002 issue of *Hepatology* that this index correctly predicted the absence of stage 2-4 fibrosis—a negative predictive value —in 96% of those with a low score below 4.2. It was not as successful in identifying the presence of fibrosis in people with high scores above 6.9 (a positive predictive value of 66%), and some patients with minimal damage were incorrectly identified as having advanced fibrosis. Furthermore, some 50-60% of patients had scores in the mid-range between 4.2 and 6.9, and could not be classified as having or not having fibrosis. But Dr. Forns' team concluded that their index could make biopsies unnecessary for about one-third of patients with mild liver disease.

To date, biochemical markers have some disadvantages. Both Fibrotest and Forns' index are very good at predicting the absence of fibrosis in people with low scores, but somewhat less so at accurately diagnosing the presence of liver damage in people

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www.hcvadvocate.org

MWC Medical Writers' Circle

Medical Writers' Circle is a publication of the Hepatitis C Support Project. It consists of a series of articles written by medical professionals about the management and treatment of hepatitis C. The articles are available for printing at the Hepatitis C Support Project website.

TREATMENT

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We know that the hepatitis C virus replicates trillion of virions a day and that constant suppression of the virus is critical, especially in patients with a high viral load (≥2 million copies/ml).

In summary, we have known for a while that it is not enough to just look at overall treatment response rates. We now know, however, that viral load and genotype should also be separated out when reporting treatment response rates. Patients and health care providers should be carefully reviewing all data, including medication, viral load and genotype as well as carefully questioning how the prospective data is being marketed and which can be misleading.

SOME FREQUENTLY USED TERMS

Genotype
genetic variation in the structure of HCV. There are six major genotypes, designated by the numbers 1 through 6. There are also many subtypes, e.g., 1a, 1b, 2a, etc. In the U.S., genotype 1 is predominant (approximately 70-75% of patients).

Biochemical response
how a person's serum ALT responds to treatment. When a patient's elevated serum ALT level becomes normal after HCV therapy has been initiated, this is considered a biochemical response.

Pegylated Interferon (PEG-INTRON, PEGASYS)
a form of interferon that has a long half-life in the body and can be injected less often (typically once per week). Pegylated interferon is approved for the treatment of HCV. See also standard interferon.

Interferon (IFN)
a naturally occurring protein in the human body produced by the immune system. Interferon interferes with viral replication. Genetically engineered products based on the natural protein have been developed by several pharmaceutical companies, and are approved for the treatment of chronic HCV infection.

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The HCV Advocate offers information about various forms of intervention in order to serve our community. By providing information about any form of medication, treatment, therapy or diet we are neither promoting nor recommending use, but simply offering information in the belief that the best decision is an educated one.

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TREATMENT

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branded ribavirin). There have not been any large head to head trials of these pegylated products but in their development programs both companies compared their pegylated combination to standard interferon plus ribavirin with almost fifty percent of the same investigator sites, so some accurate comparisons can be drawn from the data between the two PEG products as it relates to efficacy or effectiveness in certain genotype and viral load groups.

Peg Intron Plus Rebetol

Firstly, I reviewed the data on Peg Intron 1.5µg/kg plus 800mg Rebetol. Schering only conducted one combination trial, the data for which was published in *The Lancet* vol. 358, September 22nd, 2001 by Michael Manns. There is also additional supplemental information available from the FDA web site review of the Mann's data as well as the US FDA package insert (USPI) for Peg Intron. **See Table 1 for results.**

It is clear from the results shown in **Table 1** that the perceived advantage of Peg Intron plus Rebetol in genotype 1 in not entirely accurate. The overall SVR for genotype 1 patients with Peg Intron is totally driven by the improved efficacy in genotype 1 low viral load patient. Patients with genotype 1 and a high viral load (1/2 of the U.S. population with hepatitis C), will not get any increased efficacy or effectiveness over Rebetron

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TABLE 1

Sustained Virologic Response for Genotype 1

	Overall (All genotype 1 patients)	High Viral Load (>2 million copies/ml)	Low Viral Load (<2 million copies/ml)
Peg Intron 1.5µg/kg + Rebetol 800mg	42% (Lancet)	30% (USPI) 29% (FDA)	72% (FDA)
Rebetron (Intron A + 1000-1200mg Rebetol)	33% (Lancet)	29% (USPI) 28% (FDA)	44% (FDA)
Difference	**+9%**	**+1%**	**+28%**

Sustained Virologic Response for Genotype 2/3

	Overall (All genotype NON-1 patients)	High Viral Load (>2 million copies/ml)	Low Viral Load (<2 million copies/ml)
Peg Intron 1.5µg/kg + Rebetol 800mg	82% (Lancet)	72% NON-1 (FDA)	81% NON-1 (FDA)
Rebetron (Intron A + 1000-1200mg Rebetol)	79% (Lancet)	74% NON -1(FDA)	72% NON-1 (FDA)
Difference	**+3%**	**-2%**	**+9%**

TABLE 2

Sustained Virologic Response for Genotype 1

	Overall (All genotype 1 patients)	High Viral Load (>2 million copies/ml)	Low Viral Load (<2 million copies/ml)
Pegasys 180µg + Copegus 1000-1200 mg	46% (NEJM) 51% (EASL)	41% (NEJM) 46% (Roche Medical Affairs for Hadzyannis trial) 43% (USPI)	56% (NEJM) 61% (NEJM) (Roche Medical Affairs for Hadzyannis trial)
Rebetron (Intron A + 1000-1200mg Rebetol)	36% (NEJM)	33% (NEJM) 28% (FDA)	43% (NEJM)
Difference	**+10-15%**	**+8-13%**	**+13-18%**

Sustained Virologic Response for Genotype 2/3

	Overall (All genotype NON-1 patients)	High Viral Load (>2 million copies/ml)	Low Viral Load (<2 million copies/ml)
Pegasys 180µg + Copegus 1000-1200mg	76% (NEJM) 78% NON-1 (EASL 2002)	74% (NEJM)	81% (NEJM)
Rebetron (Intron A + 1000-1200mg Rebetol)	61% (NEJM)	58% (NEJM)	65% (NEJM)
Difference	**+15-17%**	**+16%**	**+16%**

Hepatitis C in Our Prisons

Kara Wright, PA-C

Conservatively, about 4 million Americans harbor the hepatitis C virus. Our 2 million prisoners are not included in this estimate. According to the Centers for Disease Control (CDC), among prison inmates, 16%-41% have serologic evidence of HCV infection, and 12%-35% have chronic HCV infection. This translates into about 240,000 to 700,000 chronically infected individuals out of 2 million inmates. Now compare this with the 1.6% for the general population.

It is difficult to determine the actual infection rate among prisoners. Many states do not routinely test for HCV. In addition, even in states that do test, many prisoners will refuse to be tested. According to states that have screened for it, anywhere from 20-60% of our prisoners are actually infected with hepatitis C. For example, Texas is faced with a 28% infection rate among male inmates and 37% rate among women inmates. California found a 39.4% HCV seroprevalence among the prison population.

According to a national study of 36 states, only one state, Colorado, routinely tests inmates for HCV. The HCV seroprevalence in Colorado prisoners is 30%.

Canada reports that the documented rate of HCV infection among prisoners continues to rise. Statistics show that in 2001, 23.6% of Canadian federal prisoners were infected with HCV.

Hepatitis C continues to be a growing epidemic, even more so than HIV. It is estimated that <1 million Americans are infected with HIV as compared to the 4 million infected with hepatitis C. Canada reports HIV infects 1.8% of their inmates and is up only 0.1% from the previous year.

The prison population is at an increased risk of contracting hepatitis C. In general, prisoners tend to engage in more risky behaviors, such as IV drug use, intranasal cocaine use and tattooing. Even while incarcerated, the infection is passed from inmate to inmate by such practices as unsterilized tattooing or piercing, violent unprotected sex, fighting with blood to blood contact, sharing of personal hygiene items such as razors and even IV or intranasal drug use which takes place behind prison walls.

Statistics show that in 2001, 23.6% of Canadian federal prisoners were infected with HCV.

The biggest obstacle to treating our prisoners is the cost of treatment. With the current medication regimes, cost per inmate could be $24,000 to $36,000 for treatment. Even if older forms of treatment were used, such as standard three times a week interferon, costs would be at least $10,000 per inmate. This would substantially burden the medical budget of prison systems today.

Another factor to take into account is that prisoners may begin treatment and be released before the end of treatment.This would often lead to treatment failure since there is often no follow up after inmate release. Many released prisoners do not have medical insurance and are unsure how to obtain medical treatment once released.

Compliance is always a concern among patients taking hepatitis C treatment. A program to ensure compliance would need to be instituted in prisons in order to help treatment success rates.

Some say prisoners are incubators for the disease and will, often unknowingly, spread the disease to others once released. Inmates who have not been tested will not know that they have a chronic infection that can be spread to others. Also, if prisoners are not treated, the disease progresses. The cost to society may be more if prisoners are not treated. We may be releasing people into the community who are sicker than when first imprisoned. Patients with more advanced liver disease obviously have more complications and incur more costs. Advocates for prisoners say that not treating inmates in need of care is both a violation of the 8th amendment (prohibiting "cruel and unusual punishment"), as well as a violation of a landmark 1976 Supreme Court ruling in Estelle v. Gamble, which determined that inmates have a right to adequate medical care for serious medical needs.

In current news, there is a pending class action lawsuit in Oregon regarding prisoners' rights to be treated for hepatitis C. The court is asking to expand testing and treatment for prisoners with HCV.

As HCV infection continues to rise, the debate will continue regarding treatment of our prisoners. Cost versus benefit will continue to be a hot topic, and pending court cases will determine their fate.

Safe Injection Sites in Vancouver, BC

CD Mazoff, PhD

On May 6th I attended a community forum on the use of supervised injection sites as a solution to curbing the spread of disease and public nuisance in Vancouver, British Columbia, Canada, by Dr. Ethan Nadelmann, executive director of the New York-based Drug Policy Alliance.

Dr. Nadelmann was invited to Vancouver by a committee of health and community outreach professionals who advocate a harm reduction-based response to drug addiction, and by Tides Canada, a national public Foundation. In attendance were representatives of Health Canada, Coast Health Authority, CTV (Canadian Television Network), CBC (Canadian Broadcasting Corporation), the former Mayor of Vancouver, Philip Owen, who designed and pushed through the safe injection site program, Dr Martin Schechter of the Canadian HIV Centre for Excellence, and other concerned groups and individuals.

The title of Dr. Nadelmann's address was, "Supervised injection sites and the four-pillar approach to drug policy: How will the U.S. respond?" Canadians, on the verge of implementing social policies such as access to medical marijuana, safe injection sites, and heroin maintenance programs are worried that the U.S. government will be vocal in its opposition to Canada's implementation of these programs. Many fear economic sanctions.

Vancouver's new strategy for dealing with a huge drug problem focuses on strengthening four "pillars"—enforcement, treatment, harm reduction, and prevention, and has shifted away from pure policing and punishment to a more compassionate and health caring model, similar to those being used in some European countries at the moment.

> ***"It is perceived that safe injection sites condone injection drug use. In fact, what safe sites do is keep people alive and open doors to healthy options like treatment and counselling that they might not otherwise encounter. Instead of making people criminals, safe injection sites help people turn their lives around and reduce the spread of deadly disease,"***
>
> *Ethan Nadelmann, PhD*

Dr. Nadelmann is a widely published scholar and former professor at some of the most prestigious universities in the world (McGill, Princeton), and so it is hard to put into a few words the salient points of an extremely well-articulated and non-stop 2 hour talk. Let me put it this way. He covered everything and he made his points, well.

In the context of trying to understand why it is that we continue to punish those who, if anything, really should be receiving support and medical treatment, Dr. Nadelmann laid the blame firmly on institutionalized racism and the drug companies who continue to profit through the sales of "good" drugs while funding programs to stop the sale of "bad" drugs.

He pointed out that there are more people in the U.S. in jails today on drug charges than the total amount of persons in jail for all charges in the European Union. He also pointed out that the prison population in the U.S. is disproportionately Black, that 25% of the U.S. Black population has lost the right to vote because they have drug related records, and that the biggest killers of Canadian Aboriginals are drugs and alcohol.

Like it or not, the gradual genocide of non White races through drug and alcohol abuse has to be seen as continuing evidence of systemic racism in North America. Why? That's another issue. Something to do with population densities. Apparently societies with smaller population densities also have less problems with substance abuse. Come to think of it, slums (composed of the poor, and the "different") are where the problems are severest.

It was also pointed out that 3 persons die a day in Canada due to some drug related cause, and that although this makes the deaths from SARS pale in insignificance, the Canadian Government immediately jumped into the SARS problem with verve and cash. Not so for the addicted.

Dr. Nadelmann tried to lay to rest the many misconceptions about supervised or safe injection sites, which actually reduce public nuisance and addicts injecting on the street.

"Some people believe supervised injection sites are evil, immoral and sick just as needle exchanges were once opposed, and that society is

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SAFE INJECTION SITES

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better off punishing addicts than helping them. But this is an extremely short-sighted view that treats drug addiction as a criminal rather than a health issue, and research proves that the criminal approach doesn't work."

Just as needle exchanges save lives and stop the spread of HIV and hepatitis C, supervised injection sites are a humane and sensible approach for injection drug use, and can be an entry point into the health system for addicts, said Dr. Nadelmann who Rolling Stone magazine called the point man for drug policy reform efforts.

"It is perceived that safe injection sites condone injection drug use. In fact, what safe sites do is keep people alive and open doors to healthy options like treatment and counselling that they might not otherwise encounter. Instead of making people criminals, safe injection sites help people turn their lives around and reduce the spread of deadly disease," he said.

I agree with Dr. Nadelmann that it is time we reduced the stigma of addiction and began to treat it as we do other diseases—diabetes—for example. The biggest problem with methadone treatment has not been that methadone doesn't work, but that unlike the diabetic who can take his or her insulin privately at home, the person on methadone treatment is dragged before the public wearing a ball and chain.

The complications and consequences of following the prohibitionist model have been costly and fatal, mostly among the poor, and the "different." The simplistic assumptions of the "just say no" approach do not work. What is needed is awareness and compassion.

For more information, please visit www.drugpolicy.org

NONINVASIVE MARKERS

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with high scores. Both algorithms are less useful in people with mid-range or indeterminate scores (though Fibrotest does yield an almost linear relationship between index scores and fibrosis). While the indices can differentiate between minimal (stage 0-1) and significant (stage 2-4) fibrosis, they cannot accurately distinguish between specific histological stages (for example, stage 2 versus stage 3). In addition, several factors other than fibrosis may affect index values. Cholesterol levels, for instance, can vary by HCV genotype. Levels of GGT and other liver enzymes tend to be higher in men than in women. Platelet count is poorly standardized among laboratories (FibroTest omits it for this reason). Most measurements can vary over time, and Dr. Keyur Patel of Duke University suggests that an average of three or more values taken over 4-6 months may yield a better number to plug into an index than a single measurement. Finally, doctors don't yet know how to use biochemical markers to gauge liver disease progression—for example, how much should an index score decrease to indicate that interferon treatment is working?

As Dr. Nezam Afdhal from Beth Israel Deaconess Medical Center in Boston notes in an editorial in the May 2003 issue of *Hepatology*, these biochemical markers do not really measure fibrosis *per se*, but rather reflect changes in liver function associated with advancing disease. However, there are other biochemical markers—including tissue inhibitor of metalloproteinase and hyaluronic acid level—that may actually reflect changes in the extracellular matrix, which accumulates as fibrosis progresses. Studies of such markers are underway, and while none have so far been found that serve as good predictors of fibrosis on their own, they may be used as part of an algorithm or index along with other variables.

Some experts believe that with new, better hepatitis C treatments that benefit more patients, liver biopsies may now be less necessary to help doctors decide who should be treated. Dr. Afdhal, for example, argues that "we can, to some extent, categorize almost a third of patients into those with mild disease and use this information for decision analysis without a liver biopsy." In an editorial accompanying the Poynard team's *AIDS* article, Dr. Vincent Soriano from Madrid and colleagues proposed that liver biopsy may be "even less justifiable" for HCV/HIV coinfected patients, since this group is more likely to experience rapid liver disease progression and appears more likely to suffer biopsy-related complications. "[M]ost patients with HCV/HIV coinfection should be considered as candidates for therapy," the researchers suggest, regardless of the extent of existing fibrosis. The discovery of new biochemical markers of liver disease progression and the development of predictive combination indices is an area of considerable promise. Concludes Dr. Afdhal, "As newer, better tolerated, and more efficacious therapies are developed, the need for biopsying all HCV patients to grade and stage disease may become redundant. Therefore, the development of noninvasive tests that can differentiate between patients with mild disease versus those with more significant fibrosis could have a widespread clinical utility in managing HCV patients in the future."

West Virginia Division of Corrections

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DEPARTMENT OF MILITARY AFFAIRS & PUBLIC SAFETY
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Ex. # 5

MEMORANDUM

TO: Donald Taylor, DOC #15593
Mount Olive Correctional Complex

THRU: Warden Thomas McBride Thomas L. McBride

FROM: Jim Rubenstein, Commissioner by
Beverly Gandee, Senior Inmate
Grievance Coordinator

DATE: June 17, 2003

RE: IG-03-221 – Denial of medical records, follow-up care and related issues.

This is an appeal of the above referenced grievance. This inmate alleges that he is being denied access to his medical records, adequate medical care, follow-up care, re-evaluation and continued medical treatment for his serious medical condition of Hepatitis C, liver disease.

Please be advised that you received a clear, correct and concise response to your grievance from Medical Administrator Mary Yelinek on May 16, 2003 and again from Warden Thomas McBride on May 16, 2003. The Commissioner can find no cause to defer from the responses you have received from MOCC Administrative Staff. Therefore, your request for relief is denied. While you may have a different opinion as to treatment modalities, we will continue to take our medical advice from those who have professional expertise in the field. If you believe that medical services are not being administered in accordance with accepted practice, you are free to seek redress via the appropriate civil court, subject to any other notice requirement provided by law.

BCG
Cc: Jim Rubenstein, Commissioner
Central Records

C.C: Records
Ms. Yelinek
Unit Team
File IG-03-